



01-02-04

Image AP/1647 #

PTO/SB/21 (08-03)

TRANSMITTAL FORM (to be used for all correspondence after initial filing)		Application Number	09/724,575
		Filing Date	November 28, 2000
		First Named Inventor	Schenk, Dale B.
		Art Unit	1647
		Examiner Name	Christopher J. Nichols
Total Number of Pages in This Submission	11	Attorney Docket Number	015270-005912US

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form (PTO/SB/17) (1 page, submitted in duplicate) <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input checked="" type="checkbox"/> Petition From Requirement For Restriction <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s)	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): 1. Return Postcard
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Firm or Individual	Townsend and Townsend and Crew LLP Rosemarie L. Celli Reg. No. 42,397
Signature	<i>Rosemarie L. Celli</i>
Date	December 30, 2003

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**FEE TRANSMITTAL
for FY 2004**

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$) 130**Complete if Known**

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Examiner Name	Christopher J. Nichols
Art Unit	1647
Attorney Docket No.	015270-005912US

METHOD OF PAYMENT (check all that apply)☐ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None☒ Deposit Account:Deposit
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☒ Charge fee(s) indicated below ☒ Credit any overpayments☒ Charge any additional fee(s) or any underpayment of fee(s)☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1)

(\$)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims		Fee from below		Fee Paid
Total Claims	-** =		X		=	
Independent Claims	-** =		X		=	
Multiple Dependent			X		=	

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2)

(\$)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)**3. ADDITIONAL FEES**

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	130
1807	50	1807	50	Petitions related to provisional applications	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid **SUBTOTAL (3)**

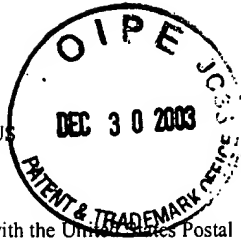
(\$)130

SUBMITTED BY**Complete (if applicable)**

Name (Print/Type)	Rosemarie L. Celli	Registration No. (Attorney/Agent)	42,397	Telephone	650-326-2400
Signature	<i>Rosemarie L. Celli</i>	Date	<i>December 30, 2003</i>		

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By: _____

Ron Anton

Ron Anton

Application No.: 09/724,575
Applicant: Dale B. Schenk
Filed: November 28, 2000
TC/A.U.: 1600/1647
Examiner: Christopher Nichols

Confirmation No.: 6096

Docket No.: 015270-005912US
Customer No.: 20350

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FROM REQUIREMENT FOR RESTRICTION

Sir:

Pursuant to 37 C.F.R. § 1.144, Applicant petitions the requirement for restriction mailed March 27, 2002 insofar as the requirement imposes "an additional restriction requirement" within individual claims of the elected Group II claims.

On December 29, 2003, Applicant filed a timely response to the Office Action mailed July 25, 2003. A notice of appeal was filed along with the response.

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BRIEF STATEMENT OF FACTS

The present case is generally directed to methods and compositions of treating amyloidogenic diseases. These diseases are characterized by deposition of a peptide into an insoluble amyloid mass. Different amyloidogenic diseases are associated with deposition of different peptides, but in each case the structure of the deposits is similar (*see* the paragraph bridging pp. 7-8 of the Amendment filed December 29, 2003, which cites to Sunde *et al.*, *J. Mol. Biol.*, 273:729-739 [1997]). In many diseases, the peptide responsible for the amyloid deposits responsible for the disease is cleaved from a precursor protein.

Claims 11-19 and 21-25 (the only claims relevant to the present petition) are drawn to methods of preventing or treating a disorder characterized by amyloid deposits by administering an agent effective to induce an immune response against an amyloid component. Claim 13 specifies that the amyloid component is derived from a precursor protein selected from a group of 15 designated precursor proteins. Claim 15 specifies that the amyloid component is selected from a group of 15 amyloid peptides.

In a restriction requirement mailed March 27, 2002, the Examiner divided the claims into groups designated I to VI. Claims 11-19 and 21-25 (discussed above) constituted the group II claims. The Examiner then imposed an "additional restriction requirement," which insofar as relevant to the group II claims, required applicant to elect one of the enumerated species in claims 13 and 15. The Examiner stated that the "additional restriction requirement" was not to be considered as a requirement for an election of species "since each of compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention" (Restriction requirement of March 27, 2002 at p. 5).

In a response of September 26, 2002, applicant elected the group II claims, and with respect to the "additional restriction requirement" elected transthyretin of claim 13 and ATTR of claim 15. Applicant traversed the "additional restriction requirement" on the basis that there was no statutory basis for requiring restriction within a single claim and that at most the Examiner should have imposed an election of species requirement.

In an office action of November 21, 2002, the Examiner maintained the "additional restriction requirement" on the basis that the "precursor proteins listed in claim 13 and their respective fragments listed in claim 15 are not members of a Markush group. Each protein/fragment pair belongs to independent and distinct diseases and disorders. Each would require an independent, non-overlapping and distinct search" (Office action at p. 2.) The Examiner also objected to claims 11-25 as containing nonelected material and required applicant to delete the same (office action at p. 5).

Applicant petitions the "additional restriction requirement" for the reasons that follow.

ARGUMENT

The restriction requirement is in error because it requires division of a generic claim contrary to controlling law. The statute authorizing restriction practice, *i.e.*, 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions.

The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim--no matter how broad, which means no matter how many independently patentable inventions may fall within it. *In re Weber et al.* 198 USPQ 328, 331 (C.C.P.A. 1978) at 334.

The claims in *Weber* stood rejected on the basis that individual claims were allegedly misjoined under 35 U.S.C. § 121 as containing multiple independent and distinct inventions and because the claims contained allegedly improper Markush groups. The court held that 35 U.S.C. § 121 does not provide a basis for an examiner to "reject a particular *claim*" *In re Weber* at 332 (emphasis in the original). The court explained that:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several

applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

In re Weber at 331.

The court also noted that the whether the claims constituted improper Markush groups was a different issue than restriction under 35 U.S.C. § 121. This issue was addressed separately by remand. (*In re Weber* at p. 331). *In re Haas*, 179 USPQ 623, 624, 625 (CCPA 1973) and *In re Haas* 198 USPQ 334-337 (CCPA 1978) followed *In re Weber* in holding that 35 U.S.C. § 121 cannot be used to reject a claim as a generic claim.

Two subsequent decisions, *In re Harnisch*, 206 USPQ 300 (CCPA 1980) and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App & Int. 1984) stated that lack of unity of invention could provide a basis for finding of an improper Markush group. However, neither case found an improper Markush group on the facts presented to it. Also nothing in these decisions changed the law of *In re Weber* and *In re Hass* that 35 U.S.C. § 121 barring the use of a restriction requirement to reject a single claim.

It should also be clear from what we have said that we adhere to our holdings in *In re Weber*, *supra*, and *In re Hass (Hass II)*, *supra*. Nothing we have said herein is intended to change or modify them in any way; nor do we think anything said could be reasonably construed to have such an effect. The "unity of invention" concept is not to be confused with the "misjoinder under 35 U.S.C. 121" rejection employed in *In re Weber*. In *Weber* we dealt with the use of 35 U.S.C. 121, which deals only with restriction requirements, to support the rejection of a single claim. Here we are concerned only with the rejection of a single claim on the distinct ground that it is directed to an "improper" Markush group.

In re Harnisch at 305.

Instead of imposing a restriction requirement on a single claim, the Patent Office may limit initial examination to a reasonable number of species encompassed by the claim. See 37 C.F.R. § 1.146. This practice strikes an appropriate balance between the concerns of the patent office regarding administrative concerns and unduly burdensome examination, and the

clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated. See MPEP (Eighth Edition August 2001, Revision 1, February 2003) at § 803.02; see also *In re Wolfrum*, 179 USPQ 620 (CCPA 1973); and, *In re Kuehl*, 177 USPQ 250 (CCPA 1973). The MPEP states that an unduly extensive and burdensome search of a generic claim justifies an election of species requirement, but says nothing about a restriction requirement of a generic claim (MPEP § 808.01(a)). The MPEP also provides that an election of species is the proper remedy if a Markush group includes independent and distinct inventions. (See MPEP § 803.02). It is acknowledged that this section of the MPEP is headed "Restriction--Markush Claims." Nevertheless, the text is explicit that an election of species is intended.

A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 102 with respect to the other members. In applications containing claims of that nature, the examiner may require *a provisional election of a single species* prior to examination on the merits.

MPEP § 803.02 (emphasis supplied).

Also, the MPEP should be construed as being consistent with the case law of *In re Weber* and *In re Haas*, as reaffirmed by *In re Harnisch*, that 35 U.S.C. 121 cannot be used to reject a single claim. Unlike a restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to file multiple divisional applications which are incapable of capturing the intended scope of the application.

Here, the "additional restriction requirement" imposed by the office action of March 27, 2002 is a *de facto* rejection of claims 11, 12, 14, 17-25. These claims do not recite Markush groups. Even if applicant was to pursue 15 divisional applications to the 15 enumerated species in dependent claims 13 and 15, the aggregate scope of the resulting claims would not be the same as that of present claim 11. Under the doctrine of claim differentiation, claim 11 is construed as being broader than claims 13 and 15 that dependent from it. Thus, if the restriction requirement were upheld neither claim 11 nor its equivalent could ever issue. The

same is true of claims 12, 14 and 17-25. Thus, the restriction requirement is directly contrary to the contrary to the controlling case law of *In re Weber* as subsequently re-affirmed by *In re Harnisch*.

The Examiner's rationale that individual claims contain many patentably distinct inventions is "no excuse at all" for purporting to restrict individual claims. *In re Weber* at 334. The appropriate remedy for an unduly extensive and burdensome search is an election of species requirement. MPEP § 808.01(a).

The Examiner's allegation that claims 13 and 15 contain improper Markush groups similarly fails to provide any basis for imposing a restriction requirement. If the Examiner believes that claims 13 and 15 contain improper Markush groups then he can reject these particular claims on that basis, and give applicant an opportunity to respond. If the Examiner believes claims 13 and 15 contain independent and distinct inventions, he can impose an election of species requirement as provided by MPEP 803.02. However, there is no legal basis supporting a remedy of a restriction requirement for an alleged improper Markush group even of the claims that recite the Markush group.

To reiterate, the allegation of an improper Markush group is entirely irrelevant to the majority of pending claims (*i.e.*, claims 11, 12, 14, 17-25) that do not even contain a Markush group.

For these reasons, it is requested that the "additional restriction requirement" be withdrawn. Insofar as the Examiner believes any Markush group is improper, it is requested that he direct a rejection to and only to the particular claim(s) containing that Markush group and allow applicant an appropriate opportunity to respond to the allegation. Applicant's position is that the Markush group is proper because the amyloid deposits formed by aggregation of the various recited peptides are similar in structure (as discuss in the Statement of Facts).


Insofar as the Examiner believes the members of the Markush groups represent independent and distinct inventions, he may impose an election of species under MPEP 803.02 and give applicants an appropriate opportunity to respond.

Application No. 09/724,575

Petition from Requirement for Restriction dated December 30, 2003

Please charge the Petition fee of \$130 to Deposit Account No. 20-1430 and deduct any additional fees from, or credit any overpayment to, the previously noted Deposit Account.

Respectfully submitted,



Joe Liebeschuetz
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